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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,682	10/19/1999	DANUTA EWA IRENA MOSSAKOWSKA	88362/107	2932

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EXAMINER	
BRANNOCK, MICHAEL T	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/380,682	MOSSAKOWSKA ET AL.	
	Examiner	Art Unit	
	Michael Brannock	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,42,49,50 and 52-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,42,49,50,52-54,57-59 and 62-64* is/are rejected.

7)☒ Claim(s) *55, 56, 60, 61, 65 and 66* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/18/03 has been entered.

Status of Application: Claims and Amendments

Applicant is notified that the amendments put forth on 11/18/03, have been entered in full. Applicant is notified that any outstanding rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments.

Maintained Rejections:

Claims 28, 50 and new claims 52-54 and 57-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No: 5545619 in view of Hourcade et al., J. Biol. Chem. 265(2)974-980, 1990, as set forth in item 9 of Paper 14, and reiterated below.

U.S. Patent No: 5545619 teaches a soluble polypeptide (CR1) comprising one to four short consensus repeats of the long homologous repeat A (LHR-A) and related polypeptides termed RCA polypeptides (see col 6), methods of producing mutations is said polypeptides (see col 7), and pharmaceutical compositions containing therapeutically effective amounts of same (see col. 9). By way of reference to Hourcade et al., U.S. Patent No: 5545619 discloses that amino acid sequences having the mutations recited in the instant claims are encompassed by the

invention (see col. 6, lines 6-15). These mutations are disclosed by Hourcade et al., (see Figure 3), as pointed to by U.S. Patent No: 5545619. Claim 42 also requires that the polypeptide derivative comprises at least two heterologous membrane binding elements with low membrane affinity, covalently associated with the polypeptide, wherein the elements are capable of interacting independently and with thermodynamic additivity with the components of cellular membranes exposed to extracellular fluids. The instant specification states that preferred membrane binding elements are basic amino acid sequences (see the bottom of page 9). The amino acid sequence taught by Hourcade et al. provides for at least 8 heterologous basic amino acids (arginine and lysine) relative to CR1 (see Figure 3 of Hourcade et al.).

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, with reasonable expectation of success, to produce a polypeptide having the amino acid sequence taught by Hourcade et al. when practicing the invention disclosed in U.S. Patent No: 5545619. The motivation to do so was provided in U.S. Patent No: 5545619 wherein it was stated that the term "RCA proteins" refers to that taught by Hourcade et al. (see col. 6, lines 6-15), and that such proteins are useful in therapeutic and prophylactic contexts (see the last paragraph of col. 8).

Applicant argues that the RCA proteins analogs which comprise CR1-4 analogs are distinct from SCR (Example 2). And that the '619 patent provides no disclosure of soluble proteins that comprise SCR3. This argument has been fully considered but not deemed persuasive. The examiner points again to column 6 of the '619 patent wherein SCRs, including SCR 3 are discussed. At col 5, line 32, soluble forms are explicitly discussed.

Applicant argues that the brief passage contained in col 7 of the '619 patent does not teach or suggest the particular set of possible amino acid substitution recited in the claims. This argument has been fully considered but not deemed persuasive. As set for above, it is the by way of reference to Hourcade et al. that U.S. Patent No: 5545619 discloses that amino acid sequences having the mutations recited in the instant claims (see col. 6, lines 6-15).

Applicant argues that Hourcade points to no usefulness of the CR1-like sequences. This argument has been fully considered but not deemed persuasive. As discussed above, it is the '619 patent that directs the artisan to the sequences provided by Hourcade.

Claims 42 and 49 and new claims 62-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No: 5545619 in view of Hourcade et al., J. Biol. Chem. 265(2)974-980, 1990, as applied to claims 28, 29, and 50 above, and in further view of Clissold et al., Eur. J. Immunol., 23(2346-2352)1993 and U.S. Patent No: 5936092, as set forth previously in item 10 of Paper 14.

As set forth previously, claims 42 and 49 and new claims 62-64contain the elements discussed above regarding claims 28, 29 and 50, yet claims 42 and 49, 62-64 also recite that the polypeptide comprise at least two heterologous membrane binding elements consisting of fatty acid derivatives. Claim 49 also requires that the process of constructing the polypeptide include recovering the polypeptide and, thereafter, post-translationally modifying the polypeptide to chemically introduce the membrane binding elements.

Clissold et al. teach that the addition of a membrane binding element (glycosyl-phosphatidylinositol, GPI) to soluble CR1 increases the effectiveness of CR1 at protecting cells

from complement mediated damage (see the abstract). Thus, Clissold et al. teach the concept that membrane binding elements increase the effectiveness of CR1. In the experiments of Clissold et al., there is only a single membrane binding element, and that element was added to CR1 during the expression of the polypeptide and not after recovery, as required by claim 49. However, the conjugation of fatty acid molecules to proteins for use in directing the proteins to the membrane of cells is well known in the art. U.S. Patent No: 5936092 discloses methods of conjugating fatty acid moieties to polypeptides for after the polypeptides have been expressed and recovered (see, for example, col. 10)

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made to post-translationally modify a polypeptide, said polypeptide being taught by Patent No: 5545619 in view of Hourcade et al., as discussed above, with membrane binding elements using the methods disclosed by U.S. Patent No: 5936092. The motivation to do so was provided by Clissold et al. who teach the concept that membrane binding elements increase the effectiveness of CR1.

Applicants arguments are based on the applicability of U.S. Patent No: 5545619 in view of Hourcade et al. have been fully addressed above. Applicant additionally argues that Clissold teach away from a soluble protein because Clissold teaches a membrane binding element which would not make the protein soluble. This argument has been fully considered but not deemed persuasive because the examiner does not understand the argument. The instant claims are directed to soluble proteins with membrane binding elements. One of skilled in the art would therefore expect that the proteins would be soluble until they bound to a membrane. Upon

binding to the membrane, they would not be in solution. This is the same principle taught by Clissold, as discussed above.

Claim Objections

Claims 60, 61, 65 and 66 are objected to under 37 CFR 1.75 as being substantial duplicates of claims 55 and 56. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Allowable Subject Matter

Claims 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-

0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (571) 272-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER

February 22, 2004